

**REMARKS / ARGUMENTS**

**I. Supplemental Response**

Claims 1-14, 16, and 20 were previously cancelled by prior Office Action responses.

Claims 15, 17-19, and 21-29 are cancelled by the present Supplemental Office Action Response and Amendment. New claims 30-55 have been added by this Supplemental Office Action Response and Amendment and are now pending.

**II. Interview Summaries**

Applicant responded to the Office Action dated December 3, 2003 (herein, the "Office Action") by filing an amendment and arguments responsive to the objections and rejections of the examiner. Subsequent to filing of its response, Applicant met with the examiner and the senior supervisory patent examiner assigned to the present prosecution on 05 April 2004. Applicant again met with the examiner on 10 May 2004. These interviews resulted in discussion with Applicant about redrafting the claims in light of all prior art of record. Applicant appreciates having the opportunity to discuss the issues in the current prosecution constructively and objectively. This Supplemental Response restates Applicant's arguments as previously submitted in the context of the new claims and, where appropriate, identifies support for the limitations of the newly added claims in the written description.

**III. Claim Objections Citing 35 U.S.C. §112**

Original claim 28 was rejected under 35 U.S.C. §112, second paragraph as failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. In particular, the examiner concluded that the limitation, "means for transmitting voice and data," lacked an antecedent. The examiner also found that the use of the "means for" language in various claims did not invoke 35 U.S.C. §112 6<sup>th</sup> paragraph.

Claim 28 has been cancelled. New claims 30, 41, 43 and 44 are means-plus-function claims meeting the requirements of 35 U.S.C. §112 6<sup>th</sup> paragraph. Applicant submits that the newly added claims address the objections of the examiner as to form.

### III. Obviousness Rejections

#### A. Generally

Various claims of the present invention have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 3,646,606 issued to Buxton et al. (herein "*Buxton*") or U.S. Patent 6,364,834 issued to Reuss, et al. (herein, "*Reuss*") in view of U.S. Patent 4,838,275 issued to Lee (herein, "*Lee*").

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP. §2142 (8<sup>th</sup> Ed., Rev. 1). The references and the applicant's disclosure must be considered as a whole. MPEP §2142.02 (8<sup>th</sup> Ed., Rev. 1).

In order to appreciate the teachings of the cited references and the present invention, it is important to establish what is meant by certain words and phrases as they are used in the references and the application. "Monitoring" connotes the collection of data, but does not convey precisely what is done with the gathered data. The *Nenov*, et al. reference cited by the examiner illustrates this point. Following numbered paragraph 2, *Nenov* describes two systems, one for "continuous EEG monitoring... and the second ... devoted to continuous monitoring of physiological parameters..." *Nenov* describes what happens to the data gathered by the monitoring systems: "Typically, these data are displayed on a computer monitor, spot checked by nurses and lost as it scrolls off the screen." *Continuous monitoring* does not equate to *continuous evaluation* of the data collected by the monitoring systems or the production of highly processed information about patients.

*Buxton*, *Reuss*, and *Lee* each describe some level of data collection. Considered as a whole, these references each set out to solve a health care related problem. *Reuss* defines the problem in terms of communication:

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There remains a need, therefore, for an integrated medical monitoring system which provides bi-directional, wide bandwidth communications between a number of elements including patient monitors, central monitoring systems, medical alert systems, and analysis systems to allow both monitoring and sharing of collected data for data intensive physiological parameters and waveforms. *Reuss*, col. 2, lines 47-63.

*Buxton* substantially shares this view:

However, a number of problems exist with respect to existing apparatus, particularly in the area of interface between measurement equipment and the medical observer who must, with a high degree of efficiency, extract measured data and act on it. A further problem area lies in presently used means for communicating data between a person and the data readout equipment. *Buxton*, col. 1, lines 9-15.

*Lee* defines a problem of obtaining diagnostic services for ambulatory, house-bound patients:

Historically, people in acute physical distress were visited in their homes by physicians who diagnosed medical problems with the aid of a few simple, crude instruments. With the advent of modern sophisticated diagnostic techniques and equipment, house calls were discontinued.

People in medical distress now must go to the physician's office or to a hospital emergency room for treatment. Adding insult to injury, the patient must often go to another facility such as a specialist's office or a testing laboratory, since the diagnostic equipment in most physicians' offices is insufficient for many diagnoses, especially of cardiovascular malfunctions.

Thus the patient while already ill--and often partly incapacitated--must travel repeatedly and sometimes on short notice to several health-care professionals. Not only does this frequently entail great effort, discomfort and cost, but in addition the stress of these efforts often accelerates the decline of the patient's health, further increasing the cost of medical care. *Lee*, col. 2, lines 30-50.

These references share the belief that if only physiological data can be delivered to the right person, the health of patients would be improved. Thus, each addresses means for gathering physiological data and distributing that data to a location or locations. This is a data-gathering paradigm that makes data available to experts. While the inventions may offer solutions to the problems set forth above, the references teach little more than extending the basic bedside monitoring and data collection to remote locations.

As Applicant has maintained throughout this prosecution, data collection and dissemination is not the only problem identified and addressed by the claimed inventions. Care of a critically ill patient requires not only monitoring by expertly trained clinicians but an appreciation of the significance of subtle changes in a wide array of monitored data captured and analyzed continuously in the context of a patient's historical, clinical, prescription and other data. Providing a stream of physiological information to a single medical professional or transmitting a threshold alarm from the monitoring equipment does not, alone, serve this need. The claimed inventions reflected in the newly added claims provide powerful analytical tools applied at the central monitoring station that utilize a variety of data types to determine if intervention is warranted. Smart alarms are also set at the central monitoring station and utilize patient-specific rules.

*Buxton, Reuss, and Lee* are the dominant references cited against the rejected claims. Applicant submits that the motivation to combine these references cannot be found in the references themselves, but is inspired by the teaching of Applicant's disclosure. The courts have recognized that such hindsight is not permissible:

"It is difficult but necessary that the decisionmaker forget what he or she has been taught . . . about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

The fact that Applicant's application has been fruitful is evidenced by the results achieved where the teachings have been practiced:

"This system has shown it can save the life of more than one patient per week in two separate intensive care units," says Steven A. Fuhrman, M.D., Sentara Medical Director for the eICU center. "The eICU system shows us each day what happens when you merge the best technology with the most qualified medical professionals."

The eICU technology by VISICU efficiently manages scarce intensivist resources while also helping to meet recently defined Leapfrog standards of quality care giving. The Leapfrog Group was formed by Fortune 500 companies and other large healthcare purchasers to monitor patient safety. Hospitals around the country are committed to meeting higher standards of care giving, including providing board certified intensivists to manage the ICU.

The eICU system has already been extremely successful in reducing mortality rates at other Sentara facilities. An independent study performed by Cap Gemini, Ernst & Young (CGEY) shows the eICU solution reduced intensive care mortality rates at Sentara Norfolk General Hospital by 25% and shortened the average length of stay for these patients by 17%. This study also revealed that Sentara's per patient costs dropped \$2,150 based on reduced patient expenses and increased ICU capacity.

Mortality rates plunged when our around the clock reaction time became a matter of seconds," says Rod Hochman, M.D., Senior Vice President and Chief Medical Officer for Sentara Healthcare. "Nothing that we have seen to date has so dramatically altered the quality of care for intensive care patients. Press Release, dated November 17, 2003, issued by Sentara Healthcare, ("Sentara Adds eICU® Technology to Fourth Hospital - Patients at Sentara Leigh Hospital's Intensive Care Units Now Under Lifesaving Care.")

Similar results were also reported and peer-reviewed in *Critical Care Medicine*, 2004, Vol. 32, No.1, pp. 31-38 wherein:

"Overall ICU and hospital mortality decreased by 26.7% ...during the intervention period." (when the present invention was used).

Further, "Average ICU LOS (length of stay) decreased 16% ..." (when the present invention was used).

The dramatic results achieved by the practice of Applicant's inventions underscore that one skilled in the art, at the time these inventions were made, "who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art" would not have been motivated to combine the references to produce the teachings of Applicant's disclosure.

Even assuming that one skilled in the art were motivated to combine the references as suggested by the examiner, regardless of how the references are combined, the combination will not successfully produce the results of the claimed inventions. This statement is supported, if not proven, by the dramatic and unexpected results derived from practicing the teachings of Applicant's disclosure as describe above.

**B. New Claims 30-45**

Original claims 15 and 18 of the present invention have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 3,646,606 issued to Buxton et al. (herein "Buxton") or U.S. Patent 6,364,834 issued to Reuss, et al. (herein, "Reuss") in view of U.S. Patent 4,838,275 issued to Lee (herein, "Lee"). Original claim 17 has been rejected as being

unpatentable over *Reuss* in view of *Lee*. Original claim 19 has been rejected as obvious over *Buxton* and *Reuss* in view of *Lee*. Original claims 15-19 have been cancelled. The elements of original claim 15 have been incorporated into new independent claim 30. The term "proactive" has been eliminated from the preamble as having no structural significance in the context of these claims. Elements of claims 17-19 have been incorporated into new claims 36-38 respectively. Applicant submits that for the reasons provided below, new claims 30-45 of the present invention are not obvious in view of the cited references.

New independent claim 30 of the present invention recites the following limitations:

A system for providing expert critical care simultaneously to a plurality of geographically dispersed intensive care units (ICUs) from a remote location, the system comprising:

a network;

a plurality of geographically dispersed ICUs comprising means for monitoring patient data elements from a patient and means for transmitting the monitored patient data elements to a remote command center by the network;

the remote command center connected to the network and comprising:

a database, wherein the database comprises stored patient data elements relating to the patient;

a computerized patient care management system connected to a workstation, wherein the computerized patient care management system is adapted for:

receiving the monitored patient data elements from the plurality of geographically dispersed ICUs;

storing the monitored patient data elements in the database;

applying a rules engine to at least two patient data elements stored in the database; and

monitoring the medical condition in the patients and utilizing the output from the rules engine to determine if intervention is warranted; and

wherein the monitoring and intervention for individual patients in the plurality of geographically dispersed ICUs occurs 24 hours per day 7 days per week.

In the rejection of original claim 15, both *Buxton* and *Reuss* were cited as disclosing remote monitoring of critically ill patients. The limitation of "a plurality of geographically dispersed ICUs" was equated to *Buxton's* disclosure of a plurality of intensive care patient units (*Buxton* Fig. 1-10) and to its disclosure that "patients may be in separate room, making unnecessary a special location for patients requiring intensive care." *Buxton*, Col. 2, lines 21-24. *Reuss* was also as cited as teaching a plurality of critical care patient monitors. (*Reuss*, Fig. 1-16;

*Reuss*, Col. 5, lines 8-10; *Reuss*, Col. 7, lines 15-25.) The critical care patient monitors were found to be the equivalent of Applicant's ICUs.

New independent claim 30 provides a system for providing expert critical care *simultaneously* to a plurality of geographically dispersed ICUs from a remote location. Thus, the present invention reflects that expert critical care may be provided in accordance with embodiments of the present invention to a number of patients requiring critical care in a variety of critical care settings.

Additionally, Applicant states: "The present invention addresses these issues and shortcomings of the existing situation in intensive care, and its shortfalls via two major thrusts. First, an integrated video/voice/data network application enables continuous real-time management of ICU patients from a remote setting. Second, a client-server database application B integrated to the remote care network B provides the data analysis, data presentation, productivity tools and expert knowledge base that enables a single Intensivist to manage the care of up to 40 patients simultaneously." Specification, page 6, lines 16-21. These and other statements in the Specification make clear that the present invention is directed to not only expert care of a single critically ill patient but for the care of a number of critically ill patients simultaneously without restriction on where that patient may receive that care.

Independent claim 30 also refers to "patient data elements." Patient data elements are monitored from a patient. The term "patient data element" is supported by various references in the Specification. For example, in the Detailed Description of the Invention section of the Specification, Applicant states: "Referring to Figure 19 the smart alarms of the present invention are illustrated. The smart alarm system constantly monitors physiologic data (collected once per minute from the bedside monitors) and all other clinical information stored in the database (labs, medications, etc)." Specification, page 39, lines 15-18.

Applicant acknowledges that the present invention may be practiced to provide expert critical care simultaneously for critically ill patients, whether they are in separate rooms, separate hospitals, or separate countries, and accepts the broad interpretation of the stated limitation. Applicant respectfully disagrees that the cited references teach the limitations of new independent claim 30.

The examiner found *Buxton* described proactive monitoring as recited in original claim

15 of the present invention. This finding was based on the following language of *Buxton*:

In the "Every Patient Continuous Monitoring" section there is continuous monitoring of ... preshock indications. There is selectable continuous monitoring of any of several conditions. *Buxton*, Col. 2, lines 29-33.

*Buxton* further defines the function performed by the "Every Patient Continuous Monitoring" section:

This permits the preset of critical limits for a given patient as determined by his doctor and thus provides selective critical care for that patient. As a still further aid to the detection of a dangerous change in heart condition, a heart signal output...is fed to preshock detector and alarm 78, which detects the presence of higher than normal voltages and energizes alarm light 79. *Buxton*, Col. 4, lines 5-11.

*Buxton* teaches manually setting static presets and issuing alarms from the bedside monitor if these presets are exceeded. The alarm is evidence that a dangerous condition is present (e.g., the presence of higher than normal voltages). The teaching of *Buxton* is limited to the evaluation of a single patient data element (a dangerous change in heart condition). This is a single event-driven process that cannot be reset from the remote location. The inventors of *Buxton* characterize their invention as follows:

The operator of the central control monitor visually scans periodically the traces on a cathode-ray display 12 corresponding to the physiological functions of each patient. The operator periodically selects between physiological signals to be observed by selector switch 80. The operator observes heart rate on a meter 72 and systolic and diastolic blood pressure on meters 81. Dangerous blood pressure excursions are indicated by preset warning lights 82 and 83 and preshock condition by alarm 78. When desired, for example, where there is indication of progressive changes in a patient, particular functions may be recorded on tape recorder 90.

The operator may also selectively observe decimal readouts for precise determination of blood pressure, for any patient. In addition, both external and internal temperature are made digitally available for examination.

In summary, by means of reasonable attention and selection a single operator is able to provide intensive and extensive observation of a number of patients, a feat not previously possible. *Buxton*, Col 5, lines 11-31.

*Buxton* is clearly a data gathering system combined with a single event-driven process that relies on alarms set at the bedside to manage "emergencies." Data is presented to a single operator and, except for certain alarm conditions set at the bedside, the evaluation of that data is



charged to the single operator. By contrast, new independent claim 30 teaches a computerized patient care management system adapted to apply a rules engine to patient data elements at the central monitoring station. Applicant further submits that *Buxton* teaches against the claimed inventions and is not prior art for the purposes of establishing a prima facie case of obviousness as directed to new claim 30 of the present invention.

As noted above, the system of new claim 30 utilizes patient data elements that are acted on by a rules engine at the central monitoring station, not by a human operator. Support for this limitation is found in the Specification:

Referring to Figure 19 the smart alarms of the present invention are illustrated. The smart alarm system constantly monitors physiologic data (collected once per minute from the bedside monitors) and all other clinical information stored in the database (labs, medications, etc). The periodicity of the collection of data is stated for illustrative purposes only. It is well within the scope of the present invention to collect physiological data at more frequent time intervals. Thus, monitor 636 provides information in HL7 form to the interface engine 638. The physiological data is then formatted by the interface engine for storage in the database 640 where all patient information is maintained. **The rules engine 642 searches for patterns of data indicative of clinical deterioration.**

One family of alarms looks for changes in vital signs over time, using pre-configured thresholds. These thresholds are patient-specific and setting/disease-specific. For example, patients with coronary artery disease can develop myocardial ischemia with relatively minor increases in heart rate. Heart rate thresholds for patients with active ischemia (e.g. those with unstable angina in a coronary care unit) are set to detect an absolute heart rate of 75 beats per minute. In contrast, patients with known coronary artery disease in a surgical ICU have alarms set to detect either an absolute heart rate of 95 beats per minute or a 20% increase in heart rate over the baseline. For this alarm, current heart rate, calculated each minute based on the median value over the preceding 5 minutes, is compared each minute to the baseline value (the median value over the preceding 4 hours). **Physiologic alarms can be based on multiple variables.** For example, one alarm looks for a simultaneous increase in heart rate of 25% and a decrease in blood pressure of 20%, occurring over a time interval of 2 hours. For this alarm, thresholds were initially selected based on the known association between changes in these two variables and adverse clinical events. Actual patient data were then evaluated to determine the magnitude of change in each variable that yielded the best balance between sensitivity and specificity. This process was used to set the final thresholds for the rules engine.

Alarms also track additional clinical data in the patient database. One alarm tracks central venous pressure and urine output, because simultaneous decreases in these two variables can indicate that a patient is developing

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hypovolemia. Other rules follow laboratory data (e.g. looking for need to exclude active bleeding and possibly to administer blood). **The purpose of the rules engine is to facilitate detection of impending problems and to automate problem detection thereby allowing for intervention before a condition reaches a crisis state.** Application, page 39, line 15, through page 40 line 23 (emphasis added by bolding).

It is well established that "a prima facie case of obviousness may also be rebutted by showing that the art, in any material respect, teaches away from the claimed invention." In re Geisler, 116 F.3d 1465, 1471, 43 USPQ2d 1362, 1366 (Fed. Cir. 1997). Because *Buxton* places the analytical burden on an observer, *Buxton* implicitly teaches against applying a rules engine to at least two patient data elements stored in a database. *Reuss* also describes a central monitoring system that continuously monitors "incoming data for possible emergency situations." When an emergency situation is found, an alert is issued. *Reuss*, Col. 4, lines 42-48. *Reuss* does not, however, describe the parameters of an emergency situation, but its clear meaning is that the patient has entered a state of high risk. Emergency handling is an event-driven process that occurs after the fact. It is not a process that uses a rules engine to determine if intervention on behalf of a patient is warranted.

*Reuss* also describes the trending of parameters:

Comprehensive trending of such parameters as heart rate, blood pressure, SpO<sub>2</sub>, respiration rate, etc. over time is available through the Trend Display Manager 55. A 24-hour trending capability is preferred. The trending can involve single or multiple parameters and is especially useful for cardiorespiratory patients, or those with other cardiovascular abnormalities. The Patient, Event, and Trend Managers together comprise the System Executive Task 208. *Reuss*, Col. 9, lines 38-46.

*Reuss* contemplates displaying a trend of one or more individual physiological parameters. The preferential period is 24 hours. No relationship between or among the physiological parameters is suggested by *Reuss* nor does *Reuss* suggest or teach relating a physiological parameter with some other data element (such as a clinical, laboratory or prescription data element). While trending of individual parameters is useful, it should not be confused with the application of a rules engine to patient data elements of a patient as recited by new claim 30 of the present invention.

As with *Buxton*, *Reuss* does not teach applying a rules engine to patient data elements at

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the central monitoring station.

*Reuss* alludes to the analysis of the transmitted data at the central monitoring system:

As mentioned above and as shown in the figures, the present invention can include an automated data acquisition and/or storage component. Such a component, in its various embodiments, can without limitation be incorporated for use in conjunction with the clinical analysis of transmitted data. This aspect of the invention can allow for the immediate clinical presentation and analysis of ECG, NIBP, SpO.sub.2, as well as other pertinent information. This automated component is preferably located in the central monitoring system 14 although it can be located in or coupled to of the patient monitors 16 or other devices. *Reuss*, Col. 7, line 59 through Col. 8, line 7.

However, the nature of the analysis is to display for a human operator data that has been recorded. *Reuss* appears to contemplate that this data will be analyzed by a person at a later time:

However, with the present invention, once the patient monitor 16 is activated, data can be acquired, stored and evaluated upon transmission/reception. For example, ECG data can be automatically stored and evaluated for comparison to future output ECG data by a central monitoring system 16. Col. 8, lines 19-24.

*Reuss* also appears to contemplate that a caregiver will analyze the collected data:

Preferably, the medical monitoring system also comprises at least one auxiliary system for transmitting and receiving clinical data, thereby providing a more complete overall medical monitoring and recordation system. The auxiliary system can be connected to the medical monitoring system via a hardwired network link, or through a wireless communication link. The auxiliary equipment can comprise a diagnostic workstation such as an ECG diagnostic workstation, a clinical information system, or other database system. Diagnostic workstations receive selected archived physiological data such as vital sign data, waveforms, timed cardiac events, or other events from the central monitoring system or a patient monitor for further clinical analysis **by a caregiver**. *Reuss*, Col. 6, lines 9-22. (Emphasis added by bolding.)

And,

As noted above, the central monitoring systems 14 communicates bi-directionally with at least one, and preferably a plurality of shared, remote access devices 200 carried by caregivers. The remote access devices 200 can request that specific data be transmitted to the access device 200 **for review by a caregiver**. Col. 15, lines 61-64. (Emphasis added by bolding.)

While *Reuss* alludes to some form of data analysis, *Reuss* does not teach or

disclose the application of a rules engine to patient data elements as recited in the claimed inventions.

The examiner also observed that *Lee* teaches against a computerized patient care management system:

Additionally, *Lee* teaches that much of the information obtained by the system is not amenable to computerized analysis and thus the observer is essential for interpretation of these data, i.e., the ballistocardiogram, the electrocardiogram, impedance pneumogram and DUSIAP trace **must be interpreted by a professional, (the observer or "intensivist") who compares the data to the stored baseline tracings, as well as lung sound requiring human monitoring.** Office Action, Paper No. 20, page 7, lines 8-14. Emphasis added by bolding.

Applicant submits that *Lee* teaches exactly the mindset that Applicant's disclosure seeks to challenge. It is inherent in *Lee*'s discussion of "2.2 Priorities" in column 8 and "4.1.2 Emergency Diagnostic Session" in column 16 that the system of *Lee* is only intended to monitor a single patient at a time, as is typically done by physicians with outpatients. According to *Lee*,

The Observer will put on "hold" all patients undergoing routine sessions in order to devote full attention to the emergency. *Lee*, Col. 16, lines 58-60.

It is inconceivable that a single observer, whether a doctor or a trained intensivist, can provide quality care to critically ill patients at various sites if that same observer is charged with monitoring data streams and evaluating the data for patterns indicative of clinical changes in the condition of each of the critically ill patients. The teachings of Applicant's disclosure challenge this old regime by providing a computerized patient care management system adapted to apply a rules engine to patient data elements at the central monitoring station and utilize the output from the rules engine to determine if intervention is warranted.

A prima facie case of obviousness as directed to new independent claim 30 of the present invention cannot be based on any combination of *Buxton*, *Reuss* and *Lee*. Applicant submits that there is no motivation to combine these references aside from the teachings of Applicant's disclosure, that combining these references is an impermissible exercise in hindsight, and that at least *Buxton* and *Lee* (if not all three references) teach against the limitations of new independent claim 30 of the present invention.

Further, one skilled in the art attempting to solve the problem faced by Applicant would have no motivation to combine *Buxton* or *Reuss* with *Lee*. That is, neither of these combinations

addresses application of a rules engine to patient data elements at the central monitoring station. For all of these reasons, new independent claim 30 of the present invention is not obvious in view of the cited references.

New claims 31-35 depend from new independent claim 30 and recite additional limitations specific to the "at least two data elements" recited in base claim 30. Each of these dependent claims recites the limitations of new independent claim 30 and new limitations not disclosed by the cited references. New claims 31-35 are thus patentable over the cited prior art.

New claims 36-39 and 41-45 of the present invention depend from new claim 30 and recite additional limitations. Claim 40 depends from claim 39. As new claims 36-45 of the present invention depend from new independent claim 30, they recite all of the limitations of new independent claim 30. For this reason, new claims 36-45 of the present invention recite limitations not taught by the cited references and are, therefore, patentable over those cited references.

**C. New Claims 46-55**

Original method claim 25 of the present invention has been rejected under 35 U.S.C. §103(a) as being unpatentable over *Buxton* or *Reuss* in view of *Lee* as applied to original claim 15 and further in view of U.S. Patent 5,724,580 issued to Levin et al. (herein, *Levin*) or U.S. Patent 6,230,142 issued to Benigno et al. (herein, *Benigno*). The elements of original claim 25 have been incorporated into new independent method claim 46. However, the term "first network" was not carried over into new independent claim 46. This was for clean-up purposes only since the reference to the "first network" in claim 25 (now cancelled) was not a meaningful structural limitation.

As with new independent claim 30, new independent claim 46 recites the limitation, applying a rules engine to at least two patient data elements stored in the database to monitor the medical condition in the patients. As demonstrated with respect to new independent claim 30, a combination of *Buxton*, *Reuss* and *Lee* does not recite this limitation.


New claims 47-55 depend from new independent claim 46 and recite the limitations of new claim 46. New claims 47-55 are thus patentable over the cited prior art.

In view of the above information and remarks, Applicant respectfully requests reconsideration of the current rejections. Applicant submits that based on the foregoing, claims

30-55 are allowable over the cited prior art. Applicant further requests that a timely Notice of Allowance be issued in this case.

Should any further questions arise concerning this application or in the event that the above amendments do not place the application in condition for allowance, Applicant respectfully requests a telephone interview. Attorney for the Applicant may be reached at the number listed below.

Respectfully Submitted,

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